

Report on Barbiturates

CURRENTLY there is a clamor and outcry in the press about the widespread misuse of barbiturates with reports of accidental deaths and demands that these drugs be placed under strict control. This is not a new complaint. It was in response to just such a note of alarm that 13 years ago the Committee on Public Health of The New York Academy of Medicine first deliberated on the value of barbiturates, the dangers of their misuse, and proper measures for their control. Two years later it formulated a code that set the pattern of control, a pattern that has been widely adopted. Now a rising chorus of protest over the existing situation has prompted the committee to reexamine the problem of barbiturates.

Definition

The barbiturates comprise a family of many chemical compounds of which barbituric acid is the parent. Some 53 years ago one of the derivatives was introduced into therapy under the name of veronal. Since then by substitution of an aliphatic or aromatic group, barbituric acid has yielded a large number of derivatives. Many have proved to be ther-

apeutically useful. Each of these has a chemical name; in addition, it has either a popular name or a registered trade name. Since barbiturates are members of a series, all have essentially the same pharmacological and therapeutic action, but each shows an individuality. Hence, there are preparations containing two or more barbiturate derivatives; each such mixture is usually marketed under a registered proprietary name. Furthermore, pharmaceutical manufacturers have added a small amount of barbiturates to mixed preparations in which they are not the main ingredient. It is said that the number of products containing barbiturates, including single, multiple, and mixed ingredients, now exceeds 275.

Use of Barbiturates

The therapeutic uses of the barbiturates are several: hypnotic, sedative, anticonvulsant, anesthetic, and adjuvant with analgesics. Thus, one or more of these substances is the active principle in sleeping pills and in some of the tension-reducing preparations. They are, however, not to be confused with the newer so-called tranquilizing drugs such as rauwolfia or chlorpromazine. (Some of the newer tranquilizing drugs

which are growing in popularity as substitutes for the barbiturates may have similar hazardous effects. They have not been considered in this report because their use is as yet too brief to warrant an authoritative statement.) The barbiturates are also an almost indispensable therapeutic agent for the control of convulsions in epilepsy. Each drug in the barbiturate group is marketed and dispensed as an individual preparation; some are included in multi-ingredient prescriptions and products. As a group the barbiturates are rated among the 10 most valuable drugs available to physicians.

Their value is reflected in the extent of their use. In view of their properties it is perhaps not too surprising that the production and sale figures are very high. The total national production of barbiturates has shown a steady increase since World War II. In addition to their increased use as hypnotics, it is believed that pharmaceutical manufacturers more and more are incorporating small sedative doses of barbiturates in mixed preparations. Ideström states that in the United States in 1948 the estimated consumption was 336 tons or 24 doses of 0.10 gm. per person as compared with an estimated consumption in 1952 in Sweden of 20 tons or 29 doses of 0.10 gm. per person.

From a study in 1954, Fazekas and Koppanyi assert that between 3 and 4 billion doses of barbiturates are legally prescribed by the medical profession in the United States annually. Assistant Commissioner Trichter of the New York City Health Department estimates that 12 percent of all prescriptions compounded by pharmacists in this city contain one or another of the barbiturates. They are also dispensed

In view of the national interest in commerce in barbiturates, Public Health Reports reprints from the June 1956 Bulletin of The New York Academy of Medicine the report of its Committee on Public Health. The report was prepared by the Subcommittee on Barbiturates: Haven Emerson, M.D., chairman, Henry Aranow, Jr., M.D., George Baehr, M.D., McKean Cattell, M.D., Hubert S. Howe, M.D., Lawrence C. Kolb, M.D., Robert W. Laidlaw, M.D., J. Murray Steele, M.D., H. D. Kruse, M.D., secretary. It was approved by Edward J. Donovan, M.D., president of the academy.

on prescription on a large scale in England and Wales as was revealed by two analyses. Dunlop and associates examined 17,301 prescriptions covering the month of September 1949 and found that 1,636 or 9.4 percent were for barbiturates. In an analysis made by the Ministry of Health of 106,295 prescriptions issued during October 1954, 8.8 percent were for barbiturates or preparations containing barbiturates. The percentage of all prescriptions in which barbiturates were the sole or principal agent in 1954 was 6.4 percent. It is apparent that these highly useful drugs are widely used.

Misuse of Barbiturates

In any consideration of misuse it is necessary at the outset to examine assertions concerning their allegedly promiscuous use. Parenthetically, it should be stated that consideration of promiscuous use at this point is restricted to usage of barbiturates at their usual hypnotic or sedative level; usage of them in excessive doses will be considered separately. By promiscuous use is meant their unrestricted, indiscriminate use when they are unnecessary, ill-advised, or contraindicated. It carries the connotation of misuse.

The allegation concerning barbiturates is twofold. It has been charged that the public is obtaining barbiturates illegally and taking them without advice of a physician; and that some physicians are prescribing barbiturates irresponsibly. The argument is based in part upon the increasing annual production of barbiturates and the calculated per capita consumption of them. Taken alone this is scarcely a reliable argument. For an increase in consumption is not necessarily *prima facie* evidence of misuse. It has already been noted that pharmaceutical manufacturers increasingly have incorporated small sedative doses of barbiturates in mixed preparations.

As for the allegation against physicians, it is the opinion of Fazekas and Koppanyi that the great volume and proportion of legally prescribed barbiturate preparations are mainly responsible for the widespread belief

that barbiturates are used promiscuously in therapeutics. From their study on whether barbiturates were being promiscuously prescribed, they concluded that physicians were using barbiturates for disturbed states because there was no specific or an equally good therapeutic product available. In the opinion of these investigators, the physicians were using the barbiturates rationally and with full knowledge of the limitations; and they were waiting only for the advancement of medical science to provide an effective therapeutic alternative or preferably replacement. Fazekas and Koppanyi predicted that if physicians had "at their disposal truly etiotropic drugs for anxiety and tension states, they would certainly not prescribe barbiturates."

The wide prevalence of psychiatric complaints among the population must add up to a large volume of legitimate therapeutic need. In applying the proper rationale to meet this need physicians have little latitude of choice. Prescriptions of barbiturates to meet this need would not per se be promiscuous. Rather, it would be a discharge of inescapable responsibility with the most effective therapy available.

Categories of Misuse

Like many things of value, barbiturates are undoubtedly misused. When there is use in excessive amounts and overdosage or in conjunction with alcohol, that indubitably is misuse. This misuse falls into five categories according to attendant circumstances.

The first type of misuse is prolonged use of barbiturates in slightly excessive amounts. Some individuals may be of such unstable personality as to rely upon barbiturates to enable them to face the real or fancied tension of their daily lives. Thus, because barbiturates afford relief from anxiety, tension, and conflicts, they lend themselves to habitual self-medication at a slightly increased dosage, particularly in disturbed states for which there is no specific therapy.

Second, barbiturates may be misused as a substitute for narcotics or

alcohol. Narcotic addicts who are temporarily unable to obtain the narcotic of their choice may turn to barbiturates. Alcoholics may resort to barbiturates to relieve the tremor and nervousness following a drinking episode. Another variety of misuse in this category is the ingestion of barbiturates following drinking of alcohol; or vice versa. Large doses of barbiturates may be taken inadvertently during a period of alcoholic intoxication. Then too, some individuals deliberately combine alcohol and barbiturates to obtain a brief but intense exhilaration, which is of course followed by profound intoxication and narcosis. This is a highly dangerous practice; for, as pharmacologists have repeatedly warned, these drugs in combination have a potentiating action which magnifies the effects of each.

The remaining three categories have to do with episodes of overdosage of barbiturates which occur either accidentally or intentionally. A person who wants only to obtain rest during a period of extreme stress may take an excessive amount of a barbiturate. Usually he is seeking a quick and full effect; he wants to make sure that he will fall into a deep sleep without delay. Perhaps he subscribes to the old adage that if a little is good, a lot is better. At the same time he is unfamiliar with the dangers of barbiturates. As a result he may increase the dosage and consume a quantity far in excess of that required to produce a night's sleep.

More frequently an unintentional overdose occurs because a person ingests additional doses after failure of the usual hypnotic dose to produce sleep. After a person takes one or two sleeping pills, he may enter into a twilight zone of mental confusion and forgetfulness instead of dropping off to sleep. In this state he forgets that he has already taken the pills; he takes more. Thus, he accidentally ingests excessive amounts of barbiturate while he is in a semi-stuporous state induced by the original dose. This sequence is known as automatism.

In addition to these episodes of overdosage which are purely ac-

cidental or inadvertent, in others the intent is suicide. Hence, barbiturates are misused as a means of self-destruction. Indeed, they are a popular choice. Yet judged by their relative effectiveness, it is a less perfect choice for the purpose than numerous other methods. Nevertheless, it represents the gravest misuse of these valuable drugs.

In sum, whatever the motive and attendant circumstances, persons may increase the amount of barbiturate ingested to the point where an episode of acute poisoning occurs. Not infrequently it terminates fatally.

Effects of Misuse

The effects of misuse of barbiturates may be considered under three headings: habituation and addiction; chronic intoxication; acute poisoning. Because barbiturates afford relief from anxiety, tension and conflicts, they lend themselves to habitual use, especially since there is no specific therapy to supersede them. There is a difference of informed opinion as to whether they should be termed addicting or habituating drugs. It may be helpful to consider a definition of terms.

To most laymen the word "addiction" simply means a bad habit. To experts it means more than that, but they differ on its definition. According to pharmacologists the significant element in addiction is dependence, either physical or emotional. Tatum and Seevers have defined addiction as "a condition developed through the effects of repeated actions of a drug such that its use becomes necessary and cessation of its action causes mental or physical disturbances." However, Isbell and Fraser do not regard this definition as acceptable to physicians and social workers who have to handle addicts. They state that the concern about addiction is "not because individuals who use drugs become dependent but because the effects of the drug are harmful both to the individual and society." This view is reflected in Vogel, Isbell, and Chapman's definition of drug addiction "as a state in which a person has lost the power of self control with reference to a

drug and abuses the drug to such an extent that the person or society is harmed."

In their review of the subject, Isbell and Fraser state that the Drug Addiction Committee of the National Research Council reached a definition of drug addiction which represents a compromise between a formulation based on dependence and that based on harm to the individual or society. It is: "Addiction is a state of periodic or chronic intoxication, detrimental to the individual and to society, produced by the repeated administration of a drug. Its characteristics are a compulsion to continue taking the drug and to increase the dose with the development of psychic and, sometimes, physical dependence on the drug's effects. Finally, the development of means to continue the administration of the drug becomes an important motive in the addict's existence."

Isbell and Fraser then point out that physical dependence is not an essential part of this definition; and that psychic dependence, although a necessary, is not a specific and distinctive characteristic. In their opinion the latter adds nothing to the definition. They express their preference to return to their original position in defining addiction "as a state of periodic or chronic intoxication in which an individual compulsively abuses a drug to such an extent that the individual or society is harmed."

While agreeing that an addicting drug produces harm to an individual or society, the committee would place emphasis on dependence and, for purposes of differentiation, particularly on physical dependence. Perhaps the best way to understand addiction is to distinguish it from "habituation." "Habituation," so far as the use of drugs is concerned, signifies an emotional dependence resulting from repeated use; administration of the drug may be discontinued without disturbance of bodily functions. In contrast, "addiction" is considered to be an altered condition of the cells, tissues, and organs of the body, brought about by the continuous administration of a drug; cessation of use causes painful physi-

cal as well as mental disturbances. In brief, habituation refers to the condition in which psychological stress appears upon abstinence; while addiction pertains to the condition in which physical signs also occur upon withdrawal.

Vogel, Isbell, and Chapman assert that barbiturates fulfill all three criteria of addiction: development of tolerance, habituation, and physical dependence. They report that when barbiturates are withdrawn abruptly from patients who have been taking 12 gr. or more daily for several weeks, convulsions and acute psychotic reactions appear. From these results they are emphatic in declaring that the derivatives of barbituric acid are addiction-producing drugs since they can bring about not only psychological but also physical dependence. It would appear therefore that physical withdrawal symptoms occur when large amounts of barbiturates have been ingested over a period of time. Under these conditions it is probably accurate to refer to barbiturate addiction.

The Expert Committee of the World Health Organization, after considering the problem, concluded "that the barbiturates must be considered drugs liable to produce addiction, [and] dangerous to public health, although differentiation among them with respect to the intensity of this liability cannot be made at this time."

After weighing all the evidence it is the opinion of the Committee on Public Health that true addiction manifested by physical dependence with withdrawal symptoms may follow prolonged high dosage of barbiturates. But, the committee emphasizes that the symptoms of addiction with barbiturates are produced only under these specific conditions; and that these conditions do not commonly occur.

Of equal if not greater concern is the question relating to potential dangers of prolonged ingestion of barbiturates in small amounts. It may be pointed out that the habitual daily use of small or moderate doses of barbiturates under medical supervision has been continued for many years without evidence of harmful

effects. Only low grade tolerance is developed under such circumstances; therefore the tendency to increase dosage to obtain adequate effects is minimal. This is a sharp point of distinction between barbiturates and opiates. Although psychic dependence on these substances may develop, it is believed not to be injurious. It is like habituation to coffee or tobacco. From these observations it is the belief of the Committee on Public Health that the habitual daily use of barbiturates at therapeutic levels, even for long periods, is not perforce injurious. It should not be necessary to add that this pronouncement does not connote approval of or condone the use of barbiturates for whatever length of time without valid reason and medical supervision.

Like almost every form of medication, barbiturates when misused are capable of producing toxic effects and even death. Through regular, prolonged use of barbiturates in excessive amounts chronic intoxication develops. The symptoms of this toxic cumulative action are mainly mental, psychic, and neurological. Specifically, these manifestations are: muscular incoordination, slurred speech, inability to perform skilled acts, as well as mental symptoms, such as confusion, abnormal behavior, impaired judgment, and possibly hallucinations.

Acute intoxication results from an overdose, either accidental or suicidal, on a single occasion. It may be mild, moderate, or severe in degree depending upon whether the person remains conscious, or becomes semicomatose, or comatose. Mental and neurological disturbances are the principal symptoms. In the severe form unless prompt and energetic therapeutic measures are instituted, the outcome may be fatal. The degree of intoxication and the issue depend on the type of barbiturate, the dosage, and the patient's constitution and physical status.

Prevalence of Misuse

It is difficult to derive accurate figures on the total prevalence of misuse of barbiturates because data in one or more categories are un-

trustworthy or unobtainable. For example, the general public seems to be familiar with the sedative and somnifacient effects of barbiturates; but no one can state reliably how many persons are obtaining barbiturates illegally and taking them in the usual or slightly higher sedative or hypnotic dose without medical supervision. (Where rates are reported, they are based on per million population, total, male, or female.)

Addiction. Reliable data indicating the extent of true addiction, that is, prolonged daily ingestion of very large quantities of barbiturates, are not available. Despite the total quantity of barbiturates used, the figure for addiction is believed to be insignificant; for, addicts are not frequently encountered. Addiction is probably limited to persons who, if the barbiturates were not available, would take excessive quantities of alcohol or other drugs.

Of 919 barbiturate poisonings in New York City in 1954, 36 were said to be in barbiturate addicts.

Poisonings. Due to inadequate report procedures the prevalence of chronic poisoning is not known. Data are therefore exclusively on acute poisonings. These may be conveniently classified under the headings nonfatal and fatal.

Nonfatal poisonings. Not all cases of barbiturate poisoning are fatal. The nonfatal cases may require treatment in a hospital. It is reported that in England and Wales the number of cases requiring hospital treatment has increased in recent years. In the United States about one-fifth of all instances of drug poisoning are due to barbiturates. It is estimated that 1 in every 2,000 admissions to hospitals is for acute barbiturate poisoning.

Figures on the incidence of nonfatal poisonings in New York City since 1945 are available by years. Under article 7, section 86 of the Sanitary Code of New York City it is the duty of persons in charge of hospitals and of physicians to report poisoning, whether acute or chronic, by drugs due to self-medication or on prescription. The nonfatal poisonings are reported to the

bureau of preventable diseases of the New York City Department of Health and from there to the poison center of the department. The rate of total nonfatal poisonings, including both categories, has risen steadily in New York City from 1945 to 1954. Indeed, it has more than doubled over that period. The rate was 35.4 for 1945; it reached 61 in 1948; and became 97 in 1954.

Nonfatal poisonings comprise two categories: poisonings under accidental or undetermined circumstances, and unsuccessful suicidal attempts. Lockett and Angus, reviewing 64 consecutive cases entering Oldchurch Hospital in England in the 4 preceding years, found that 49 at least were suicidal attempts. Moreover, of all cases of attempted suicide admitted alive during the 4 years, barbiturates were the chosen agents in more than 80 percent.

Analysis of the rates of nonfatal poisonings in New York City between 1945-54 reveals that unsuccessful suicidal attempts constituted the major category every year, sometimes by a ratio of 2:1. The rate for attempted suicide was 22.4 per million living population in 1945; it became 42 in 1948; it rose to 58 in 1950; it dropped to 37 in 1952; and returned to 57 in 1954. In contrast, the rate for accidental and undetermined nonfatal poisonings did not exceed 20 per million population until 1949; it became 30 in 1953; and 40 in 1954. It is apparent that the rate of total nonfatal poisonings has increased and that unsuccessful suicidal attempts contribute the major portion.

Fatal poisonings—total deaths. The data on deaths from barbiturate poisoning are much more reliable than those on morbidity. Figures are available for England and Wales, the United States, and New York City.

For England and Wales the rate of total deaths from barbiturate poisonings was 1.36 in 1939, and remained between the range of 1.7 to 2 until 1945 when it became 2.5. Thereafter it has increased steadily to become 13 in 1954 (fig. 1). If the 5-year period from 1939-43 is compared with a later period of similar

length, 1950-54, the average rate of fatal poisonings during the latter shows a sixfold increase, 1.8 versus 10.5.

In the United States the rate for total deaths from barbiturate poisoning was 3.23 in 1939, and remained in a range not exceeding 4.3 until 1945 when the rate was 5.7. It reached 7.6 in 1949; thereafter it declined and has remained between 6 and 6.5 from 1951 through 1954 (fig. 2). If the average rates for two 5-year periods are compared, 1939-43 and 1950-54, it is found that the figure for the later period is slightly less than twice as high, 3.6 versus 6.5.

For New York City the rate was 5.7 in 1939; it gradually increased to 9 in 1943; it jumped to 17.7 in 1944; it reached 27.3 in 1950; it declined slightly over the next 3 years; and then rose to 25.9 in 1954 (fig. 3). The average rate for the period 1950-54 was 24.3; it was 3 times

higher than the average rate of 7.4 for the earlier span, 1939-43.

Comparison of the three sources of data reveals that the rate for total deaths from barbiturate poisoning was higher in New York City for every year from 1939 through 1954 than were the rates for either England-Wales or the United States (fig. 4). From 1939 to 1949 the rate for the United States was higher than that for England-Wales. Thereafter the reverse was true. For 1954 the rate for England-Wales was about twice as high as that for the United States. The comparative order of average rates for 1950-54 was: United States 6.5; England and Wales 10.5; New York City 24.3.

For both males and females in England and Wales the rate of fatal poisonings has risen steadily from 1939 through 1954 (fig. 1). Except for one year, the rates for females were slightly higher. The average rates for the period 1949-53 were:

male, 8.1; female, 10.2. Figures on the distribution of fatal poisonings by sex in the United States are available only from 1949 through 1953. During that period the rates for both sexes declined; the rates for females were slightly higher than for males (fig. 2). The average rates were: male, 5.7; female, 7.7.

Until 1944 the rate for fatal poisonings for males in New York City ranged between 6 and 7.7; in 1944 it jumped to 17; in 1950 it reached a high point of 27.7; and declined thereafter to a value of 23 in 1953 (fig. 3). The rate for females was 5.3 in 1939 and increased steadily until it reached 10.7 in 1942; it jumped to 18.4 in 1944; and reached its peak of 31.3 in 1946. For the next 7 years it fluctuated rather narrowly between 20.3 and 23.1 except for the year 1950 when it was 27. Up to 1948 the female rate was higher than the male but thereafter the male has been higher. The average rates for the 5-year period 1949 through 1953 were: male, 24.4; female, 23.2.

Fatal poisonings comprise two categories: death under accidental or undetermined circumstances and suicide.

Death under accidental circumstances. For England and Wales the rate for accidental death from barbiturate poisonings was 0.3 in 1939, and rose gradually to become 4.1 in 1954 (fig. 1). For the United States the rate for fatal barbiturate poisonings under accidental circumstances was 1.5 in 1939; it remained at approximately that level until 1945 when it reached 2.8; its high point was in 1949 with a rate of 3.1. In 1951 it declined and from 1952 to 1954 it was 2.1 (fig. 2).

The trend of rates for New York City over the same period has been highly irregular (fig. 3). The rate for fatal poisonings under accidental circumstances was 2.4 in 1939; it reached three peaks of 10.1, 10, and 12 in 1943, 1950, and 1952 respectively; and then dropped precipitately to 3.1 in 1954. For each of the three census areas the average rate of the period 1939-43 compares with that of 1950-54 as follows: England and Wales, 0.74 to 3.34;

Figure 1. Deaths from barbiturates in England and Wales, 1939-54, rate per million population.

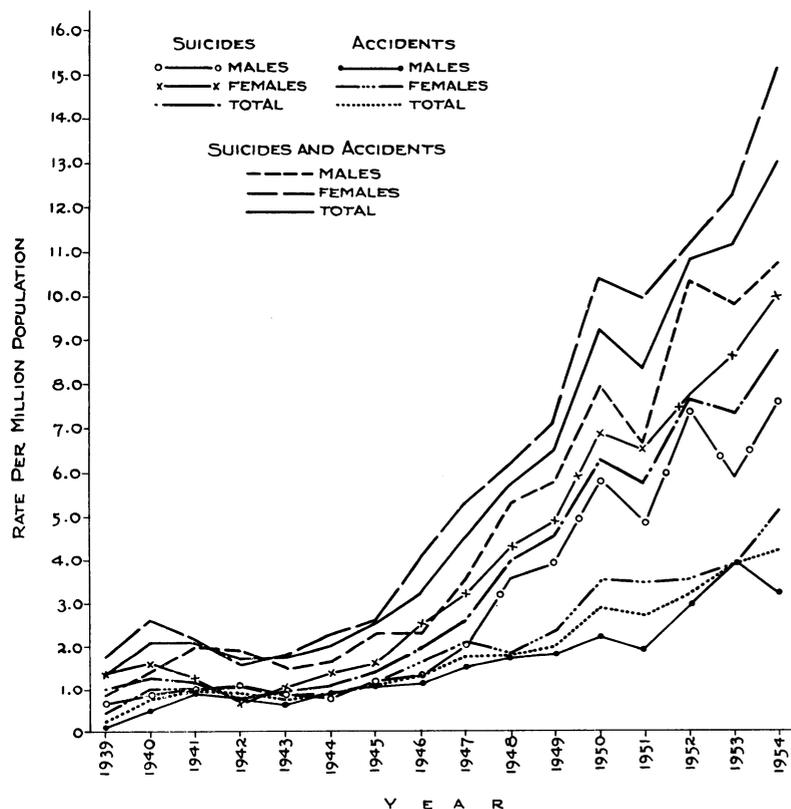
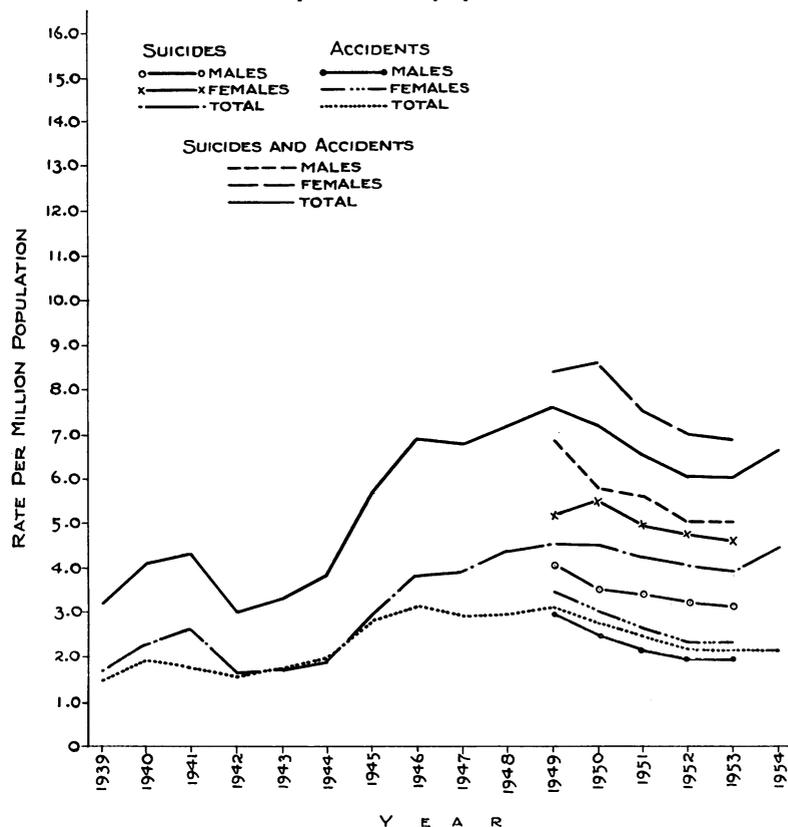


Figure 2. Deaths from barbiturates in the United States, 1939-54, rate per million population.



United States, 1.65 to 2.27; New York City, 3.1 to 8.2. It may be seen that in England and Wales the rate increased almost fivefold; in the United States, 1½ times; and in New York City, 2½ times.

Comparing the three sources of data over the years 1939 through 1954 the rates were highest in New York City (fig. 4). Up to 1950 the rates were higher and thereafter lower for the United States than for England and Wales.

The sex distribution of rates for fatal barbiturate poisoning under accidental circumstances in the data of England and Wales shows a higher figure for females for all except 4 of the 16 years (fig. 1). In 1939 the rate was 0.2 for males, 0.5 for females; in 1954, 3.2 for males and 5.1 for females. The average rates for the period 1949-53 were: male, 2.5; female, 3.3. During that period in the United States the rates for both sexes declined (fig. 2). In 1949 they

were 2.9 for males and 3.4 for females; in 1953 they were 1.9 for males and 2.3 for females.

For New York City from 1939 through 1943, the rate for males fluctuated narrowly between 2.5 and 3; it became 6.6 in 1944, and from 1946 through 1953 it was within the range 7.7 to 9 except for 1950 when it was 11 and 1952 when it was 11.5 (fig. 3). The rate for females from 1939 through 1953 had a general trend upward but it fluctuated with peaks at several points. From 1939 through 1941 it did not exceed 2.9; over the next 3 years it ranged between 4.4 and 5.4; it had peaks of 11.8 in 1946, 9.1 in 1950, and 12.5 in 1952; then dropped to 8.4 in 1953. The male rate was in excess of the female rate for 10 of the 16 years, but the course was irregular. The averages for the period 1949 to 1953 were: male, 9.5; female, 8.6.

From 1918 to 1930 accidental and undetermined fatal poisonings from

morphine exceeded in absolute numbers those from barbiturates. After that period a reversal in the ratio occurred. For example, in 1922 the ratio was 5:1 with morphine predominant. In 1954 the ratio was likewise 5:1 but barbiturates were predominant.

Deaths from suicide by barbiturates. In England-Wales during the period from 1939 through 1954, the suicide rate by all methods tended to fluctuate within a narrow range without showing a definite upward or downward trend. The rate for suicide from barbiturate poisoning, however, after having remained fairly uniform up to 1945, then underwent a rapid rise (fig. 1). Starting at 1 in 1939, the rate became 1.4 in 1945 and reached 8.8 in 1954. If the 5-year period from 1939 through 1943 be compared with a later period of similar length, 1950 through 1954, the average rate of deaths by suicide increased sevenfold, from 1 to 7.1 per million.

In the United States the suicide rate from barbiturate poisoning fluctuated from 1.6 to 2.6 from 1939 to 1944, inclusive; thereafter it rose steadily to reach a level of 4.5 during 1949 and 1950; it declined slightly during the next 3 years and then moved upward to 4.4 in 1954 (fig. 2). The average rate for 1950-54 was double that for 1939-43; 4.2 compared with 2.

In New York City from 1939 through 1943, the rate for suicide by barbiturate fluctuated narrowly between 3.2 and 5; it jumped to 12 in 1944 and moved rather unevenly to reach 22.8 in 1954 (fig. 3). The average rate for 1950 through 1954 was almost 4 times that for 1939 through 1943; 16.1 as against 4.3 per million.

Upon comparing the three sources of data over the 16-year period 1939 through 1954, the rates are found to be in the following ascending order: the United States, England-Wales, New York City (fig. 4). For the last 5 years of that period the average rate for England-Wales has been 1.7 times that for the United States; that for New York City has been 2.2 times that for England-Wales and 3.8 times that for the

United States. In 1939 Hamburger noted that in the United States the incidence of suicides was nearly twice as high in large cities as in the whole Nation.

The sex distribution on the suicide

rate by barbiturate poisoning for England-Wales shows that for the period 1939-54 the rates for female suicides have with the exception of 1 year been higher than those for the males. The average rates from 1949

through 1953 were: males, 5.6; females, 6.9. Contrastingly, when total suicide rates by all methods are considered, the male rates have been consistently in excess of the female. From 1949 through 1953 in the United States the rates for barbiturate suicides for the females were consistently slightly higher than for the males. The averages were: males, 3.4; females, 5. The distribution by sex of the suicide rate from barbiturate poisoning in New York City from 1939 through 1953 does not show a consistent trend. The averages for the period 1949 to 1953 were: male, 14.9; female, 14.6.

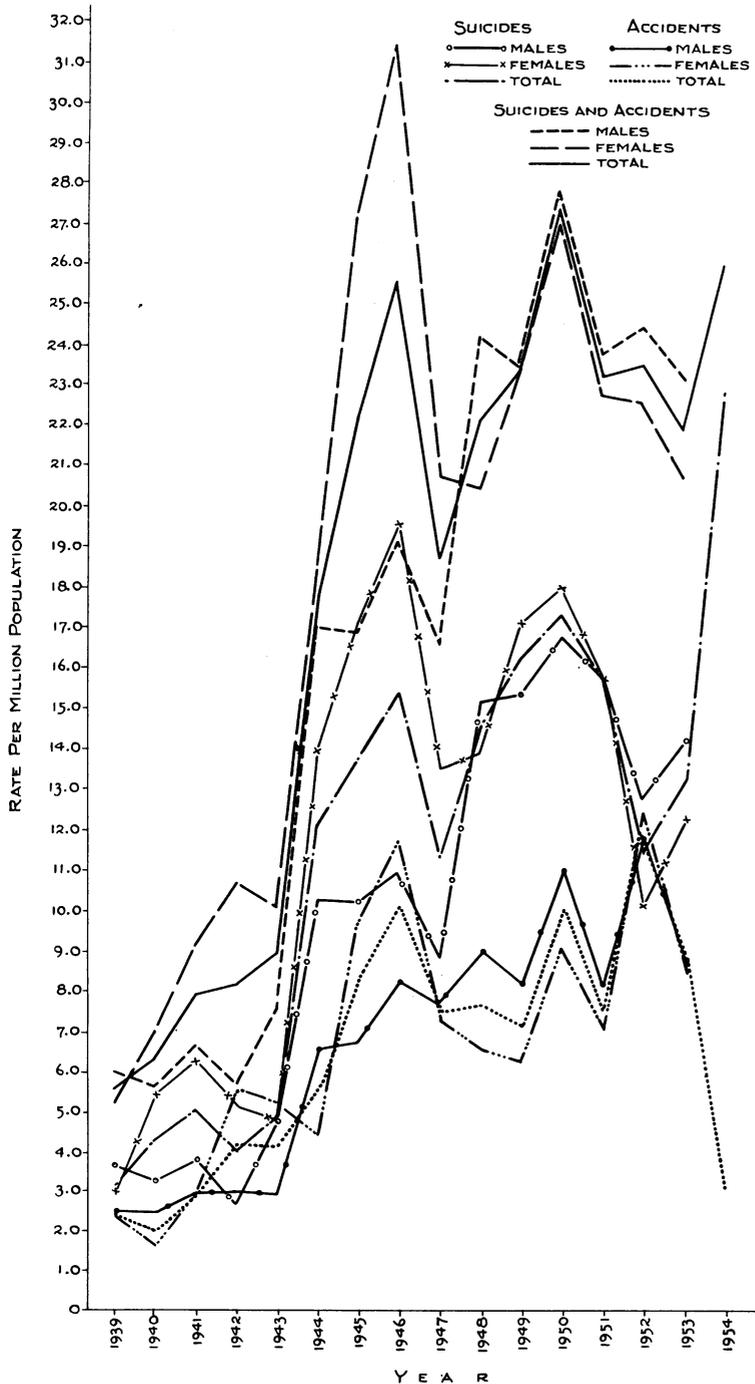
From a study of the England-Wales data Brooke found that the increase in suicide rates from barbiturate poisoning from 1942 to 1954, inclusive, was more pronounced at ages 45 and upwards. In the age group 45-64 the rates for 3 years by sexes were: 1942, males, 1.6, females, 1.5; 1948, males, 7.3, females, 8.6; 1954, males, 14.9, females, 18.1. The rates in the age group 65 and over were: 1942, males, 0.6, females, 0.4; 1948, males, 5.1, females, 6.3; 1954, males, 12.8, females, 24.4. It was remarked that it was in these age groups that one would expect to find most of the cases of depression and insomnia for which barbiturates might be prescribed.

The distribution of the death rate from barbiturate poisoning on the basis of attending circumstances yields striking results. Of the average death rates from barbiturate poisoning during 1950 to 1954, inclusive, in England and Wales, the United States, and New York City, the percentages due to suicide were respectively: 67.6, 64.6, and 66.2. Thus in all three areas suicides account for about two-thirds of the deaths from barbiturate poisoning.

From the England-Wales experience, Brooke commented that a preference has been shown lately for using barbiturates as suicidal agents rather than some other lethal means. This is likewise true in New York City where of recent years barbiturates have become the method of choice for suicide.

Total poisonings, nonfatal and fatal. From the data on total poisonings in New York City, both

Figure 3. Deaths from barbiturates in New York City, 1939-54, rate per million population.



fatal and nonfatal, from 1945 to 1954 inclusive, it is found that the rate was 57.6 in 1945; it increased steadily until it reached 111.1 in 1950; for the next 3 years it was below 100; but in 1954 it reached the peak of 123.3 per million living persons. The rate for 1954 was more than twice that of 1945. Of 491 cases of barbiturate poisoning in

New York City studied by occupation, 40 percent were in housewives, theatrical performers, clerks, unemployed and factory workers with housewives leading all others combined in this group by almost 2 : 1.

The total rate may be separated into two categories: nonfatal and fatal poisonings under accidental and undetermined circumstances; attempted suicide and suicide. It is interesting to examine the composition of this total rate to ascertain the trend and proportion of each component.

Nonfatal and fatal poisonings under accidental circumstances. Barbiturate poisonings under accidental circumstances, both nonfatal and fatal, in New York City have shown an upward trend with some fluctuation over the 10-year period 1945-54. The rate in 1945 was 21.4; in 1954, 43.4. Thus, over this span the rate has more than doubled.

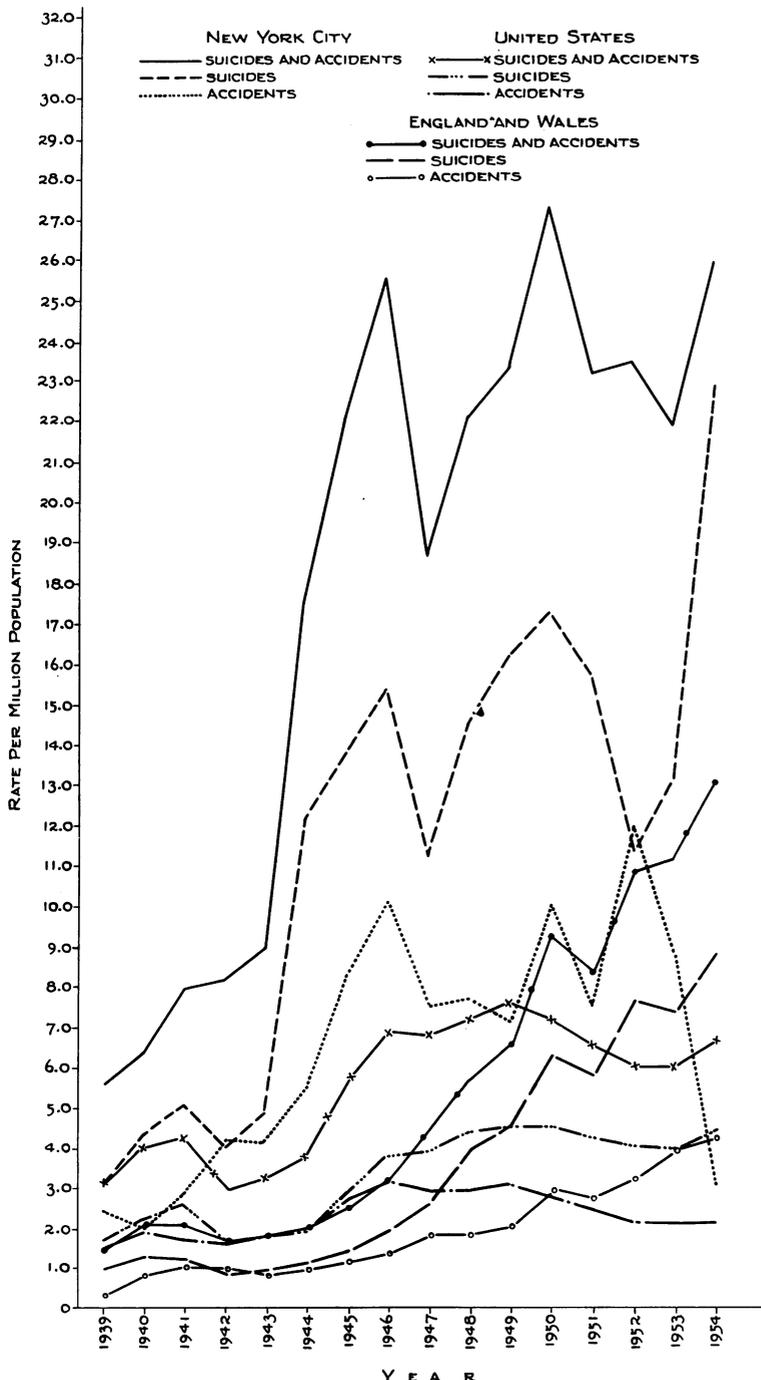
Attempted suicide and suicide. The rate for attempted suicide and suicide from barbiturate poisoning in New York City was 36.2 in 1945; it increased steadily to reach 75.7 in 1950; it declined during the next 2 years; and then resumed its climb to reach 79.8 in 1954. Here again the rate over the 10-year span has more than doubled.

For every year from 1945 through 1954, the rate for combined suicidal attempts and suicide was greater than that for combined nonfatal and fatal poisonings under accidental circumstances. In four of the years the rate was more than twice as high for attempted suicide and suicide than it was for poisonings under accidental circumstances. Over the 5-year period, 1950-54, almost two-thirds of the barbiturate poisonings, both fatal and nonfatal, were by self-destructive intent rather than by accident.

Source of Supply

It is abundantly clear that there has been an increase in the use of barbiturates; it is equally apparent that it has been accompanied by an increase in the misuse of them. But there is sharp difference of opinion over the source of supply which contributed to the misuse. It is con-

Figure 4. Deaths from barbiturates in New York City, United States, and England and Wales, 1939-54, rate per million population.



venient to consider this issue over the source under the headings: misuse of a prescription, and misuse without a prescription.

Misuse of prescription. To be considered under this topic is the charge that many of the prescriptions for barbiturates are unwarranted, ill-advised, or contraindicated. This point has already been discussed under promiscuous use. The extent to which prescriptions include barbiturates was also cited there. It has been pointed out that from such information as is available the physician is prescribing barbiturates justifiably for symptomatic relief in patients who have actual complaints, and that if specific remedies were available he would gladly turn to them.

Sleeplessness and tension are probably the two most frequent complaints for which the physician prescribes barbiturates. Locket and Angus report that in 62 out of 64 cases of barbiturate poisoning, the barbiturate was prescribed for the patient by his medical practitioner; and in more than 90 percent it was given for insomnia either alone or as the major complaint. Certainly such a therapeutic measure by a physician is neither irrational nor unwarranted. On the contrary, the physician is performing his professional duties by the best method available to him.

Another part of the same charge concerning prescriptions for barbiturates is based on their being a source of supply for suicides. Of the 64 patients with barbiturate poisoning reported by Locket and Angus, 49 were suicidal attempts; 9 had made one or more previous attempts. Nineteen were diagnosed as having a severe depressive state; 12 had severe social and domestic disturbances. Some of the patients had previously been in mental hospitals. All had obtained barbiturates by prescription. On studying the source of supply in 718 cases of barbiturate poisoning in New York City, Trichter found 52 percent had obtained the barbiturate on prescription from a physician.

In these instances, critics question whether the prescriptions for bar-

biturates were not ill-advised and contraindicated. The inference is that the physician may have exercised poor judgment and failed to establish adequate precautions. A fair, pertinent, and significant question is: What would have happened to patients who committed suicide by a barbiturate if the physician had not prescribed it? It is not improbable that they would have obtained it from another source or would have chosen another means of self-destruction.

This opens up the entire subject of suicides, not just those from barbiturates. It is beyond the scope of this report to go into that subject in all its ramifications. But for present purposes it should be stated that some patients may give no indication of contemplated self-destruction. Furthermore, when patients issue threats or declare intentions, they seldom utter them in the presence of the physician, and the family either dismisses them or fails to transmit the information. Consequently, all too frequently the physician is not alerted to the possibility of suicide. Moreover, not all persons who issue threats carry them out. Thus it is not easy to reach a decision about the probability of suicide in a patient. Nor is the course of preventive action simple and unobstructed. The patient, or the family, or both, may resist recommendations of supervision and institutionalization. What is virtually demanded is an infallible method of detecting prospective suicides and of thwarting their plans, often without recourse to hospitalization. This, the physician does not have. Yet he must try to bring relief to patients from their complaints. When the situation is viewed in its broad frame, it is at least an open question whether the physician's prescription for a barbiturate to relieve insomnia, anxiety, or tension is ill-advised or contraindicated on the grounds that the patient might commit suicide.

The second type of alleged misuse of prescriptions for barbiturates is the charge that the therapeutic prescription from the physician is very often for amounts beyond the immediate need of the patient. It is probably true that in an attempt to re-

lieve the patient of expenditure of time and money in repeated office visits, the physician may issue prescriptions for barbiturates in excess of the patient's immediate need. Unfortunately, some patients either cannot or will not exercise due judgment in taking the medication as directed; some may save their pills for suicidal purposes. The *Lancet* has reported on two persons who committed suicide, both of whom had been given a fortnight's supply of barbiturates. One had received 72 tablets 10 days before his death, of which only 4 remained. There are no data to indicate the frequency with which physicians prescribe barbiturates in unreasonably generous amounts.

As a third type of misuse of prescriptions it is said that pharmacists and physicians collaborate in dispensing barbiturates indiscriminately but technically in a legal manner. It is asserted that the pharmacists sell barbiturates to persons with no prescription at the time of sale but subsequently the transaction is covered by a collaborating physician who provides a prescription without seeing the patient.

In the fourth type of misuse of prescriptions, the pharmacist is alleged to dispense barbiturates beyond the amount specified in the prescription. Commenting on the seeming unreasonableness of having to return later for an additional supply, the customer asks whether a greater amount than specified in the prescription can be sold. It is conceivable that some pharmacists may yield to accommodating the customer by meeting his request.

At present there are no figures to indicate the number of instances in which these various types of misuse of prescription occur. By some there is said to be flagrant abuse and that it constitutes a considerable source of supply for potential misuse. Others regard this source of supply as negligible.

Without a prescription. In considering source of supply there is another category comprising the various ways in which barbiturates are obtained without a prescription. Three different types of procedure fall under this heading. In the first,

the retail pharmacist is said to dispense barbiturates without a prescription. Where there are legal provisions which require the pharmacist to keep records on the purchase and distribution of barbiturates, these violations are detectable and subject to prosecution. However, the inadequacy of enforcement even in these areas makes the figures on violations extremely unreliable.

The second source of supply without a prescription is from friends and neighbors who usually act from a motive of helpfulness. When a person complains of insomnia or anxiety, a well-intentioned friend with a similar complaint may provide barbiturates out of his supply.

The third source of supply of barbiturates, it is asserted, is illegal traffic with a black market. By some this is regarded to be the major source of supply of barbiturates and responsible for most of the potentialities of misuse. It is alleged to be a vast, gigantic operation. In an article on the subject the *New York World-Telegram and Sun* detailed the four channels which operate outside the usual pharmaceutical routes. First in the illicit trade are export-import firms which obtain their supply from the wholesale druggist. All that the export-import firm needs is a letterhead and a telephone number; for these may be the only credentials on which the wholesaler checks. A second type of illicit operation is by deception and misrepresentation in which supply houses and even pharmaceutical houses are the victims. A person interested in peddling barbiturates at a fantastic profit has a fictitious physician's letterhead or prescription blank printed and on the basis of it places orders with supply houses. The third source of supply which is said to fall into illegal channels is samples for physicians. Reputedly there are 200 different brands of sleeping pills and 1,300 drug houses compound and package one or more preparations. In order to encourage the sales of their products, these companies regularly send samples to physicians. A widespread amount of these products is

said to contribute to the vast illicit traffic.

On the other hand, this image of a vast illegal traffic is not shared by all authorities. Some assert that there is no evidence of production of barbiturates in the United States designed exclusively for illicit sale. They add that although the extent of diversion of barbiturates from legitimate to illegitimate channels is unknown, the infrequency of charges of this practice would lead to the belief that it is comparatively small.

Previous Recommendations

In 1943 in the belief that barbiturates were being sold indiscriminately, the commissioner and deputy commissioner of health of New York City requested the Committee on Public Health to consider the subject and to recommend a solution. At that time the Sanitary Code of New York City included barbiturates among the harmful drugs which could not be dispensed without a written prescription. It further provided that any prescription containing barbiturates should not be renewed or refilled by a pharmacist if it bore any indication to that effect.

The health department was of the opinion that in the indiscriminate use of barbiturates the supply was from two sources: (1) over-the-counter sale by pharmacists; (2) refilling of prescriptions by pharmacists. As a possible control of the second source the deputy commissioner suggested an alternative: (1) to prohibit the refilling of all prescriptions containing barbiturates, a procedure that admittedly might be highly unpopular; or (2) to undertake an educational campaign among physicians to make more frequent use of their prerogative to limit prescriptions to a single filling. The opinion of the Committee on Public Health was sought concerning the desirability of these proposals.

The committee stated its belief that it was inadvisable to prohibit the refilling of all prescriptions containing barbiturates since such a

policy would work an undue hardship on those patients who might be required to use barbiturates continuously; for example, epileptics. As for the alternative course of action, the committee doubted whether physicians should be asked to antagonize patients by writing "nonrefillable" on prescriptions inasmuch as the physicians' motives would certainly be misconstrued.

The committee recognized two other methods by which the sale of barbiturates might be further controlled: (1) the Sanitary Code might be revised to provide that prescriptions for barbiturates should not be refillable unless the physician indicated otherwise; and, (2) prescriptions for barbiturates might carry an expiration date of 6 months or perhaps a year. Exceptions might be made for prescriptions in which the barbiturate was not the main ingredient.

After consideration of all the aspects, the committee reached the conclusion that the use of barbiturates did not then constitute a sufficient problem in public health to warrant the adoption of any measures for restriction beyond those then in the Sanitary Code. It was believed that the production of barbiturates was not unduly large in view of the number of epileptics. Moreover, the committee reasoned, further control of the sale of barbiturates would not materially reduce the number of suicides, since a person bent on self-destruction by barbiturates could go from physician to physician in order to obtain a sufficient quantity or could resort to other methods of suicide. The committee summarized its position: "In view of the fact that the barbiturates do not present a large public health problem from the point of view of suicides, toxic psychoses, addiction, or chronic poisoning, and since the suggestion for the further control of their sale by the department of health would either work a hardship on those who must use these drugs almost continuously, or would place physicians in an unnecessarily difficult position, or would prove unenforceable, the committee is of the opinion that no revision in the Sanitary Code should

be recommended at the present time."

Because of the reported growth of illicit trade in barbiturates and the increase in accidental poisonings and suicides by them, the Committee on Public Health in 1945 at the request of the commissioner of health of New York City again considered the desirability of extending restrictive measures regarding their sale and distribution. The commissioner submitted to the committee a draft of proposed regulations which had been formulated in cooperation with the New York office of the Federal Bureau of Narcotics.

After studying the problem and the suggested proposals, the committee came to the conclusion that stricter measures of control over the sale and distribution of barbiturates were warranted. The suggested extension of control, however, was not to operate to interfere with the freedom of physicians in their practice; rather, it was aimed to guard against misuse of barbiturates by the dispenser and the user.

The committee recommended the following specific regulations:

1. Prescriptions should be refillable when so indicated by the issuing physician; but such prescriptions should indicate a minimum interval between renewals and the total number of renewals. No prescription containing a barbiturate should be refilled after 6 months from the date of issuance.

2. Pharmacists should not reveal the content or furnish copies of prescriptions to patients.

3. Prescriptions should carry suitable information about the identity of the patient and the prescriber.

4. In an emergency a physician should be allowed to transmit to a pharmacist by telephone a prescription for not more than six average doses of barbiturate drugs provided a written prescription is supplied to the dispensing pharmacist within 72 hours. Should the pharmacist fail to receive such a written confirmation, he should notify the health department of the omission.

5. Proper records of dispensed barbiturates should be kept by physicians, dentists, and veterinarians.

6. Manufacturers, wholesalers, and jobbers should maintain suitable records of sales and distribution, and inventories of stocks.

7. Pharmacists should keep records of bills of purchase of barbiturates and copies of prescriptions on which such drugs were dispensed, including notation of amounts dispensed upon refilling.

8. Barbiturates should not be supplied to any person except on prescription or in the course of legal sale within the drug trade.

All of these recommendations in either their original or a slightly varied form were incorporated into the Sanitary Code by the end of 1947. They are presently in force.

Legislation

New York City

Prior to October 11, 1922, the Sanitary Code contained no specific provision concerning the sale of barbiturates. They were regulated by the provisions applicable to all other drugs. These regulations included:

1. Registration with the New York City Department of Health of non-prescriptive proprietary and patent medicines;

2. Provisions against misbranding, imitation, and substitution; against false and misleading statements; and against failure to disclose alcohol, narcotics, chloroform, chloral hydrate, and acetanilid;

3. Prohibition against dispensing a prescription, decoction, and medication under false or misleading name, direction, or pretense.

In 1922 the board of health adopted section 126 of the Sanitary Code which was entitled "Veronal, etc. sale regulated." This section forbade the sale at retail, except upon written prescription, of veronal, veronal sodium, luminal, and luminal sodium, together with sulphonal, tuinal, and tetranol. Additionally, these substances were designated by chemical name, and provision was made that the section apply to these drugs by whatever name called or known.

In 1940 the Sanitary Code was amended by section 116 on prohibition of manufacture and sale of

adulterated and misbranded drugs which incorporated the provisions of section 502 of the Federal Food, Drug and Cosmetic Act of 1938. This section applied to all drugs.

In the same year the Sanitary Code was further amended by section 118 which regulated more fully the sale of barbiturates in New York City. Barbiturates were included among the drugs which could not be dispensed without a written prescription, and this prescription could not be refilled if it bore an indication to that effect.

The 1945 recommendations of the Committee on Public Health were for the most part adopted by the board of health in 1947 as amendments section 118 b, c, d, and e to the Sanitary Code. Differences from the recommendations were: The life of the original prescription was reduced to 3 months. The recommendation requiring physicians to keep records of barbiturates dispensed was not adopted. Instead, labeling of the container by the physician dispensing barbiturates was specified. The provision allowing for filling of a telephone prescription for barbiturates did not appear in the amendments of 1947 but was adopted in 1948.

New York State

There was no specific legislation on barbiturates or other hypnotic or somnifacient drugs prior to 1939. In that year the Education Law was amended by addition of section 1360a entitled "Hypnotic and Somnifacient Drugs" which by definition included barbiturates. The basic requirement was a written prescription. Later in 1939, article 51 regulating the practice of pharmacy was completely revised to incorporate the provisions of the Federal Food, Drug and Cosmetic Act of 1938 with respect to drugs and cosmetics. During this revision section 1360a was repealed. No specific legislation on barbiturates was again introduced into the Education Law until 1945.

In 1945 a new section 1366a, entitled "Hypnotic and Somnifacient Drugs" was introduced into the Education Law. By definition this section again included barbiturates

and in the main duplicated section 1360a of the 1939 law. The basic requirement was a written prescription. In 1946 section 1366a was newly entitled "Barbiturate and Other Hypnotic and Somnifacient Drugs" and was expanded to essentially its present form. In 1947 following a new revision of the Education Law, section 1366a was renumbered to section 6814. Minor changes were made in the phraseology of the section; and numbering of the subsections was standardized.

Section 6814 has continued to the present without change. It is dissimilar to the committee's recommendations in several respects:

1. It permits a prescription for barbiturates to be refilled unless it bears a direction to the contrary. If the prescriber fails to specify "not to be refilled" or an indication of the refillable time period, then the prescription may be refilled during a period of not more than 6 months. Furthermore, the prescription shall not be refilled prior to the end of the period for which the medication should last.

2. It carries no provision for the physician to dispense barbiturates directly to the patient.

3. It contains no provision requiring the pharmacist to keep records of bills for purchase of barbiturates; and,

4. It does not require manufacturers, wholesalers, and jobbers to maintain a record of amounts of barbiturates received, distributed, or sold.

Section 1747b of the Penal Law of New York State entitled "Sale or Possession of Barbiturate Drugs or Preparations" carries a penalty for unauthorized sale or possession of barbiturate drugs or preparations.

Other States

The Drafting Committee of the Council of State Governments drafted a model bill entitled "Hypnotic or Somnifacient (sleep-producing) Drugs Act" which appeared in its report on Suggested State Legislation Program for 1955. The council is the research and law writing agency of the Conference of State Governors which is held an-

nually to consider methods of achieving greater economy and efficiency in State government. This model law is similar to the recommendations by the Committee on Public Health except in the following particulars: Although it requires that refilling of a prescription must be specifically authorized, it does not specify a minimum interval between renewals, the total number of renewals, and the expiration date of the prescription. On the other hand, it includes a section on penalties. One of the provisions in the model law is similar to that recommendation of the Committee on Public Health which was not adopted in the Sanitary Code; namely, the physician must maintain records of barbiturates distributed by him.

In response to a questionnaire on the model law, the council heard from 34 out of 48 States. Alabama, California, Iowa, Maine, New Jersey, North Carolina, South Carolina, Texas, and Wisconsin indicated that legislation substantially similar to the draft of the model law was approved in each State prior to 1955. Indiana, Massachusetts, Montana, Nebraska, and Rhode Island have indicated that legislation substantially similar to the model act was passed during the 1955 legislative sessions.

Federal

Federal control over the sale of barbiturates is exercised by the United States Food and Drug Administration through application of the misbranded drug and device provisions of the Federal Food, Drug and Cosmetic Act of 1938, sections 502 and 503. Prior to 1951, Food and Drug Administration prosecutions for the sale of barbiturates without prescription rested on the charge of misbranding under section 502 which specified 10 types.

Of these the following four covered in section 502 (b), (d), (e), and (f) should be especially considered: A drug and device in packaged form shall be deemed to be misbranded:

1. Unless it bears a label containing the name and place of business of the manufacturer, packer, or dis-

tributor; and an accurate statement of the quantity of the contents.

2. Unless the label on a narcotic or hypnotic substance bears its name and quantity; and the statement "Warning—May be habit forming." By the terms of the section barbiturates are defined as habit forming.

3. If it is not designated solely by a name recognized in an official compendium, unless its label bears the common or usual name of the drug or each active ingredient, including the quantity or proportion of substances specified in the subsection.

4. Unless its labeling bears adequate directions for use and such adequate warnings against use in instances where it may be unsafe. Under the accompanying regulation of this fourth provision, shipment or delivery of prescription drugs, including barbiturates, were exempted if the label contained the statement "Caution: Federal law prohibits dispensing without prescription."

Section 503 (b) of the Federal Food, Drug and Cosmetic Act of 1938 provided that drugs dispensed on prescription were exempt from the first and third labeling requirements. This section further provided that if the prescription was marked non-refillable or refill was prohibited by law, the drug dispensed was exempt from the requirements that the label carry the name and quantity of narcotic or hypnotic substance, and the statement "Warning—May be habit forming."

In 1951 section 503 (b) was amended by the so-called Durham-Humphrey Act which replaced the previous provisions of that section. This new section provides essentially that:

1. A drug intended for use by man which:

- (a) is a habit-forming drug to which section 502 (d) applies [narcotic and hypnotic substances]; or

- (b) because of its toxicity or other potentiality for harmful effect, is not safe for use except under supervision of a practitioner licensed by law to administer such a drug; or

- (c) is a new drug limited to use under the professional supervision of a practitioner licensed by law to

administer such a drug, shall be dispensed only:

(i) upon a written prescription, or

(ii) upon an oral prescription reduced promptly to writing and filed by the pharmacist, or

(iii) by refilling any written or oral prescription if the refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist.

A drug dispensed contrary to above provisions shall be deemed misbranded.

2. Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from misbranding as specified in section 502, except as to false and misleading labeling, imitation of another drug, substitution, and packaging requirements, if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, the name of the patient, the directions for use, and any cautionary statements contained in the prescription.

3. The administrator may by regulation exempt habit forming drugs and new drugs from prescription requirements, when these are not necessary for the protection of public health.

4. A drug which is subject to the prescription requirement shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement: "Caution: Federal law prohibits dispensing without prescription." A drug not subject to prescription shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement.

The United States Food and Drug Administration now uses section 503 (b) (1) in prosecuting violative sales of prescription drugs, including sales of barbiturates. It has been noted that the statement "Warning—May be habit forming" was formerly required on labels for both stock and dispensing containers of

barbiturates except when the prescription was marked "nonrefillable" or its refilling was prohibited by law. Under revised section 503 (b), as provided in the Durham-Humphrey Act, barbiturates dispensed on legal prescription do not require the statement "Warning—May be habit forming" on the label of the dispensing container.

It will be noted that the Federal law, while placing barbiturates on the prescription list, controls their manufacture and distribution by specifications of misbranding. Except for the requirement of a prescription, this approach is separate and distinct from that recommended by the Committee on Public Health. Even in the requirement for a prescription, there is no restriction on refilling, such as the minimum interval, number of refillings, and life of the prescription.

When the Durham-Humphrey Act went into effect in 1952, pharmaceutical associations and pharmacy boards in 11 States decided that the laws in their States which control the sale of drugs should be amended to bring them into conformity with the Federal statute. This action was proposed in order to eliminate the confusion to which druggists were subjected in operating under two conflicting statutes. The laws of these States were in conflict with the Federal Durham-Humphrey Act on one or both of two points: prohibition against refilling of barbiturate prescriptions, and against filling telephoned prescriptions, both of which are permitted under the Durham-Humphrey Act.

Whenever State and Federal laws conflict, the stricter law prevails. Unaware of this, some pharmacists have thought that because the Federal law permits the refilling of barbiturate prescriptions and the filling of telephoned barbiturate prescriptions, such practices are proper even though the State law bans them. Harmonizing of the laws would end this confusion. In 20 States no amendment was needed to bring their laws into conformity with the Durham-Humphrey Act. Furthermore, the model State law on barbi-

turates does not conflict with Federal regulations.

Discussion and Conclusions

It is clear that the incidence of both fatal and nonfatal barbiturate poisoning is of such a magnitude that it constitutes a problem in public health. Because it includes poisonings both under accidental circumstances and from suicidal attempt, any plan for reduction must take cognizance of these two separate aspects. It is further evident that the rate of incidence is very much higher in New York City than in the United States.

As a solution to the barbiturate problem there has been a loud demand for Federal supervision, variously expressed as stiffer Federal laws, tighter Federal control over distribution, Federal regulations similar to those for narcotics. But both commercially and pharmacologically, barbiturates are dissimilar to narcotics. It should be remembered that narcotics come from a foreign source and that the basis of control is a revenue measure. In contrast, the barbiturates are domestically produced and the model act now in effect in some States and proposed for all is much stricter; in fact, it could not with reason be much more strict. Certainly the Harrison Act for narcotics is not appropriate for or applicable to barbiturates. If what is wanted is more restrictive Federal legislation because of seeming legal inadequacy in some States, the model act for States should be carefully studied before clamoring for a Federal panacea.

Another form of demand for Federal regulation is that the Narcotics Bureau be given enough money and personnel to carry out a program to control the manufacture, distribution, and sale of barbiturates. To place this responsibility on a bureau that is already overburdened with the gigantic task of coping with illicit narcotic traffic would add an additional handicap that would indeed be formidable. It is asserted that the Narcotics Bureau is most inadequately supported for its present work. Here again the present status

of enforcement of existing State and city laws and the possibilities for the future might well be explored before turning the responsibility too quickly over to a Federal bureau.

It is the opinion of the committee that the model law for States to control barbiturates, which is patterned after its recommendations of 1945, is a highly effective legislative measure containing adequately restrictive provisions. The fault lies not in the terms of this law; indeed, it is much more restrictive and in its approach is capable of exerting much more control than are the existing Federal statutes.

Rather, the present inadequacies in controlling barbiturates are of another kind. They are four in number: First, the model law has not been adopted by all; indeed, not by a majority of the States. This is not just a matter of gross negligence or apathy. It takes time to achieve legislative remedies for social problems. But before judging the adequacy of the model law and the capability of the States to control barbiturates through it, it would seem reasonable that the law be on the books. How can effective control be expected when only 13 States have adopted the measure? How can New York City enforce its model regulations to greatest effect, assuming that it had sufficient personnel, when the rest of New York State and some of the adjoining States are exempt? In view of the demonstrated magnitude of barbiturate poisoning in New York City, the blocking of these loopholes is important. Because of the apparent concentration of the barbiturate problem in urban areas, large cities with home rule in the various States should also have laws patterned after the model act.

Second, in those States which have accepted the model law, it has been so recently adopted that its enforcement has in all probability not reached the level that might be hoped for. But time is not the only reason. Even in New York City with its highly restrictive regulations in effect since 1947, it would require considerable temerity to argue that enforcement has been exemplary. Nor should the health department be

criticized or censured. To examine properly the records of manufacturers, wholesalers, jobbers, and pharmacists requires an adequate staff of inspectors. For this the department has never had the necessary number of personnel. It has only 20 pharmacy inspectors, burdened with many other duties, to patrol 4,000 retail pharmacies and 500 jobbers, wholesalers, and packagers. It is absurd to demand more stringent laws when there is so little provision for enforcement of sufficiently strong existing measures in the Sanitary Code of New York City. More laws will not compensate for an insufficient number of inspectors.

Nor would a vast force be required. A reasonable number of inspectors engaged full time and regularly in auditing the records of pharmacies, wholesalers, and jobbers might soon instill honesty among all transactors, particularly if the element of surprise was utilized. By much the same system bank examiners have exercised a salutary influence. The problem of barbiturate poisoning in New York City has been shown to be proportionately much greater than it is in the Nation. Therefore, if the situation in New York City were improved, it would go far toward reducing the national incidence of barbiturate poisoning.

It is believed that the misuse of barbiturates is concentrated in urban areas, particularly large cities; accordingly, it follows that enforcement efforts should be concentrated there. For that a Federal Bureau is not needed.

Third, ignorance and a casual attitude have been the prevailing atmosphere surrounding barbiturates. The public has been unaware that this valuable family of hypnotics, like almost all other medication, is not without its dangers when misused. Those who know the risk of misuse, the physician and the pharmacist, have apparently not adequately informed or sufficiently impressed the patients about it.

Even after studying the figures on prevalence of use and misuse of barbiturates, the source of supply, and the legislative controls, the

committee is convinced that it has not yet come to the core of the situation. Why is there widespread use and misuse of barbiturate-containing sedatives and sleeping pills? There must be a reason. That widespread practice must be symptomatic of an underlying condition. The committee can only come to the conclusion that there exists all too much unrest, anxiety, and tension in the public.

Under these circumstances, such a radical step as prohibiting the use of the therapeutically valuable barbiturates on the grounds that it would remove a means of self-destruction would not be a sensible action or a sure corrective. With equal reason it might be argued that all high bridges and buildings should be razed, and all gas lines should be disconnected. True, it is an imperative duty to throw every reasonable safeguard around the use of barbiturates. Nevertheless, that is not a true remedy which will bring effective and permanent relief. At best it is treating the symptoms of a disease, not its cause. Now perforce it is the main recourse.

But there must also be a more fundamental approach to the solution. What is needed is a means of preventing the prevalent unrest and anxiety. For that it is necessary to have knowledge about the causes of the emotional manifestations that so abound in society. Furthermore, effective prevention of suicide can come only through an understanding of the factors that bring about a morbid state that leads to a desire for self-destruction. Knowledge on these points can only come through research. Until recently the amount expended for research on mental and emotional disorders was so infinitesimally minute as to be insignificant. Even now the manpower and funds for investigations in this area are so limited in comparison with the transcendent importance of the subject as to make the need a clarion challenge.

In sum, the committee concludes that available model legislation is adequately restrictive, but it has not been widely enough adopted; where it has been put into effect, it has not been enforced. Moreover, such

widespread usage of barbiturates can only indicate extensive unrest, anxiety, and tension in the people. The methods to prevent this situation are still unknown. Finally, the public's knowledge and the general attitude about barbiturates do not now appear to be conducive to a more temperate and reasonable use of barbiturates.

Recommendations

As rational steps toward stopping the misuse of barbiturates and especially reducing the present high rate of incidence of barbiturate poisoning, the Committee on Public

Health offers the following recommendations:

1. The model law controlling the manufacture and distribution of barbiturates should be adopted by all the States. Large cities with home rule should also have laws patterned after this act.

2. A realistic effort toward enforcement of the model law when enacted is an essential step. An adequate staff of inspectors to examine records should be organized. Efforts at enforcement should be concentrated on the large cities, where the rates of incidence of barbiturate poisoning are highest.

3. An educational campaign

should be conducted by health departments, and medical and pharmaceutical societies to remind their members of their responsibility of acquainting patients with the dangers of misuse of barbiturates. At the same time there should be a campaign, using all media, to inform the public of the risks attached to the misuse of barbiturates.

4. Above all, it is highly desirable that adequate funds should be provided to support research on the causes of unrest, anxiety, and tension that are so prevalent among the population and are the basis for such great use and misuse of barbiturates.

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